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PTO/SB/21 (02-04)
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U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. Application Number 10/750,570 Filing Date TRANSMITTAL December 30, 2003 First Named Inventor **FORM** Reddy, Satyanarayana, G. Art Unit 1614 . (tobbe used for all correspondence after initial filing) **Examiner Name** Not Yet Assigned Attorney Docket Number Pages in This Submission 60188CON2449947) Total Number 1 ENCLOSURES (Check all that apply) After Allowance communication Drawing(s) Fee Transmittal Form echnology Center (TC) ppeal Communication to Board of Fee Attached Licensing-related Papers Appeals and Interferences Appeal Communication to TC Petition Amendment/Reply (Appeal Notice, Brief, Reply Brief) Petition to Convert to a After Final Proprietary Information Provisional Application Power of Attorney, Revocation Affidavits/declaration(s) Status Letter hange of Correspondence ddress Other Enclosure(s) (please **Extension of Time Request** Terminal Disclaimer identify below): **Express Abandonment Request** Request for Ref x Information Disclosure Statement CD, Number of CD(s) Certified Copy of Priority Document(s) Remarks Response to Missing Parts/ Form PTO/SB/08a/b (3 pages) Incomplete Application Certificate of Express Mailing (1 page);
Information Disclosure Statement (2 pages, in duplicate);
Copies of references A18, A19 and B4; Response to Missing Parts under 37 CFR 1.52 or 1.53 Transmittal (1 page) and; Return Receipt Postcard STGNATURE OF APPLICANT, ATTORNEY, OR AGENT EDWARSS & ANGELL, LLP Þeter 🕊. 🕽 auro - 32,360 Individual name Signature Date July 12, 2004

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Dated: July 12, 2004

Signature

_(Peter C. Lauro, Esq.)

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Daled: July 12, 2004

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Signature:

(Peter C. Lauro, Esq.)

Docket No.: 60188CON2(49947)

(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of: Reddy, Satyanarayana G.

Application No.: 10/750570

Filed: December 30, 2003

For: Cyclic Ether Vitamin D3 Compounds,

1α(OH)3-EPI-Vitamin D3 Compounds and

Uses Thereof

Confirmation No.: 572

Art Unit: 1614

Examiner: No Yet Assigned

INFORMATION DISCLOSURE STATEMENT (IDS)

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. §§1.56 and 1.9 Applicant hereby invites the Examiner's attention to the references listed on the attached form PTO/SB/08, in connection with the examination of the above-identified patent application. Applicant respectfully requests that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This application is a continuation application of application serial no. 10/188,320, filed on July 1, 2002, abandoned, which is a continuation application of serial no. 09/617,881, filed on July 17, 2000, issued as U.S. Patent 6,479,538, which is a divisional application of application serial no. 09/079,942, filed on May 15, 1998, issued as U.S. Patent 6, 00,294, which in turn claims priority to provisional application serial no. 60/046,690, filed of May 16, 1997

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Pursuant to 37 C.F.R. §1.98(d), copies of the remaining references listed on the PTO/SB/08 are

not enclosed because these references were submitted to, or cited by, the Office in information disclosure statements filed in one or more of the above-identified priority applications, and those statements complied with paragraphs (a)-(c) of 37 C.F.R. §1.98

In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists. In accordance with 37 CFR 1/97(h), the filing of this Information Disclosure statement shall not be construed to be an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

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Dated: July 12, 2004

Respectfully submitted,

Peter C. Lauro, Esq.

Registration No.: 32,360 EDWARDS & ANGELL, LLP

P.O. Box 55874

Boston, Massachusetts, 02205

(617) 439-4444

Attorney for Applicant

Customer No. 21874

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 1 of 3

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Complete if Known				
Application Number	10/750570			
Filing Date	December 30, 2003			
First Named Inventor	Reddy, Satyanarayana G.			
Art Unit	1614			
Examiner Name	Not Yet Assigned			
Attorney Docket Number	60188CON2(49947)			

	U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No.¹	Document Number Number-Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear		
	A1	4,021,423	05/77	Baggiolini et al.			
	A2	4,038,272	07/77	Partridge, Jr. et al.			
	А3	4,188,345	08/80	DeLuca et al.			
	A4	4,206,131	06/80	Salmond			
	A5	4,595,776	06/86	Baggiolini et al.			
	A6	4,711,881	12/87	Ikekawa			
	Α7	4,804,502	02/89	Baggiolini et al.			
	A8	5,145,846	06/92	Baggiolini, deceased et al.			
	A9	5,206,229	04/93	Calverley et al.			
	A10	5,206,230	04/93	Ikekawa et al.			
	A11	5,389,622	02/95	Posner et al.			
	A12	5,401,733	03/95	McLane et al.			
	A13	5,428,029	06/95	Doran et al.			
	A14	5,547,947	08/96	Dore et al.			
	A15	5,789,607	08/98	Okabe			
	A16	5,824,811	10/98	Kubodera et al.			
	A17	5,830,885	11/98	Posner			
	A18_	6,100,294	08/00	S.G. Reddy			
	A19	6,479,538	11/02	S.G. Reddy			

	FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No.1	Foreign Patent Document Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear				
	B1	EP 808,831	11/97						
	B2	EP 808,833	11/97						
	B3	FR 2545824 A	11/84						
	B4	AU 743514	05/02	S.G. Reddy					

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. **CITE NO.: Those patent(s) or publication(s) which are marked with an double asterisk (**) next to the Cite No. are not supplied because they were previously cited by or submitted to the Office in a prior application relied upon in this application for an earlier filing date under 35 U.S.C. 120. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gog or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is

	NON PATENT LITERATURE DOCUMENTS				
Examiner Initials	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²		
_	C1	Baggiolini, E. et al., "Stereocontrolled Total Synthesis of 1α25-Dihydroxycholecalciferol and 1α,25-Dihydroxyergocalciferol," <i>J. Org. Chem.</i> 51:3098-3108 (1986)			
	C2	Bishop, J. et al., "Profile of Ligand Specificity of the Vitamin D Binding Protein for 1α,25- Dihydroxyvitamin D ₃ and its Analogs," <i>J. Bone & Mineral Res.</i> 9(8): 1277-88 (1994)			

Examiner Signature	/Taofiq Solola/	Date Considered	11/17/2008

PTO/SB/08a/b (08-03)
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Substitute for form 1449A/B/PTO				Complete if Known		
				Application Number	10/750570	
- IN	VEORMATION	1 DI	SCLOSURE	Filing Date	December 30, 2003	
STATEMENT BY APPLICANT			APPLICANT	First Named Inventor	Reddy, Satyanarayana G.	
				Art Unit	1614	
(Use as many she ets as necess ary)			necess ary)	Examiner Name	Not Yet Assigned	
Sheet	2	of	3	Attorney Docket Number	60188CON2(49947)	

Bouillon, R. et al., "Biologic Activity of Dihydroxylated 19-Nor-(Pre) Vitamin D ₃ ," <i>J. Bone &</i>
Mineral Res. 8(8):1009-15 (1993)
Bouillon, R. et al., "Structure-Function Relationships in the Vitamin D Endocrine System," Endocrine Reviews 16(2): 200-57 (1995)
Campbell, M. et al., "Vitamin D ₃ Analogs and Their 24-Oxo Metabolites Equally Inhibit Clonal
Proliferation of a Variety of Cancer Cells but Have Differing Molecular Effects," J. Cellular Biochem. 66:413-25 (1997)
Cota, J.G. et al. "Hydrotitanation-Protonation of Vitamin D ₂ and Its Analogues: An Efficient Method for the Preparation of 10,19-Dihydrovitamins D ₂ Including Dihydrotachysterol ₂ " <i>Journal of Organic Chemistry</i> 53(26):6094- (1988).
Cross, H. et al., "Vitamin D Metabolism in Human Colon Adenocarcinoma-derived Caco-2 Cells: Expression of 25-Hydroxyvitamin D ₃ -1α-hydroxylase Activity and Regulation of Sidechain Metabolism," <i>J. Steroid Biochem. Molec. Biol.</i> 62(1):21-8 (1997)
de Vos, S. et al., "Effects of Potent Vitamin D ₃ Analogs on Clonal Proliferation of Human
Prostate Cancer Cell Lines," <i>The Prostate</i> 31(2):77-83 (1997)
Dusso, A.S. et al., "On the Mechanisms for the Selective Action of Vitamin D Analogs,"
Endocrinology 128(4):1687-92 (1991)
Fioravanti, L. et al., "Synthetic Analogs of Vitamin D ₃ Have Inhibitory Effects on Breast Cancer
Cell Lines," Anticancer Research 18:1703-8 (1998)
Fleet, J. et al., "1a,25-(OH) ₂ -Vitamin D ₃ Analogs with Minimal in <i>Vivo</i> Calcemic Activity Can
Stimulate Significant Transepithelial Calcium Transport and mRNA Expression in <i>Vitro</i> ," Archives of Biochem. & Biophysics 329(2):228-34 (1996)
Fleet, J.C. et al., "Effect of A-Ring Diastereomers of 1α,25-Dihydroxy Vitamin D ₃ on Calcium
Transport in Caco-2 Cells," FASEB J. 9(3):168 (1995)
Gardner, J. et al., "Vitamin D Analog 25-(OH)-16,23E-Diene-26,27-Hexafluoro-Vitamin D ₃
Induces Differentiation of HL60 Cells with Minimal Effects on Cellular Calcium Homeostasis," <i>J. Cellular Biochem.</i> 63:500-12 (1996)
Jung, S. et al., "1,25(OH) ₂ -16ENE-Vitamin D ₃ is a Potent Antileukemic Agent with Low
Potential to Cause Hypercalcemia," <i>Leukemia Research</i> 18(6):453-63 (1994)
Kim, H. et al., "1,25-Dihydroxy-Vitamin-D ₃ Enhances Antiproliferative Effect and Transcription
of TGF-β1 on Human Keratinocytes in Culture," <i>J. Cellular Physiol.</i> 151:579-87 (1992)
Lemire, J. et al., "1,25-Dihydroxy-24-OXO-16ene-Vitamin D3, a Renal Metabolite of the
Vitamin D Analog 1,25-Dihydroxy-16ene-vitamin D3, Exerts Immunosuppressive Activity Equal
to its Parent Without Causing Hypercalcemia in vivo," <i>Endocrinology</i> 135(6):2818-21 (1994)
Mayer, E. et al., "23,25-Dihydroxy-24-oxovitamin D ₃ : A Metabolite of Vitamin D ₃ Made in the
Kidney," <i>Biochemistry</i> 22)(8):1798-1805 (1983)
Muralidharan, K.R., "Studies on the A-Ring Diastereomers of 1Alfa, 25-Dihydroxyvitamin D ₃ ,"
J. Organic Chem. 58(7):1895-1899 (1993)
Norman, A. et al., "Demonstration That 1β,25-Dihydroxyvitamin D ₃ is an Antagonist of the
Nongenomic but not Genomic Biological Responses and Biological Profile of the Three A-ring Diastereomers of 1α,25-Dihydroxyvitamin D ₃ ," <i>J. Biol. Chem.</i> 268(27):20022-30 (1993)
Okamura, W.H. et al., "Studies on vitamin D (Calciferol) and Its Analogues 13," J. Organic

Examiner /Taofig Solola/	Date	11/17/2008
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Application Number Filing Date	10/750570 December 30, 2003
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First Named Inventor	Reddy, Satyanarayana G.
Art Unit	1614
Examiner Name	Not Yet Assigned
Attorney Docket Number	60188CON2(49947)
Ar	t Unit xaminer Name

C	21	Reddy, G.S. and Tserng, KY, "Calcitroic Acid, End Product of Renal Metabolism of 1,25- Dihydroxyvitamin D ₃ Through C-24 Oxidation Pathway," <i>Biochemistry</i> 28:1763-9 (1989)	
. 0	222	Reddy, G.S. et al., "Metabolism of 1a,25-Dihydroxyvitamin D ₃ and One of its A-Ring	
		Diastereomer 1a,25-Dihydroxy-3-Epivitamin D ₃ in Neonatal Human Keratinocytes," <i>Vitamin D:</i>	
		A Pluripotent Steroid Hormone: Structural Studies, Molecular Endocrinology and Clinical	
		Applications, Proceedings of the Ninth Workshop on Vitamin D, Orlando, Fl., 172-3 (May 28-June 2, 1994)	
C	23	Reddy, G.S. et al., "Stimulation of 24R,25-dihydroxyvitamin D ₃ Synthesis by Metabolites of	
1		Vitamin D ₃ ," <i>Am. J. Physiol.</i> 245(4):E359-64 (1983)	
C	24	Reddy, G.S. et al., "Study of 1,25-Dihydroxyvitamin D ₃ Induced Alterations in the Metabolism	
		of [³ H]25-Hydroxyvitamin D ₃ Using Isolated Perfused Kidneys From D-Sufficient Rats,"	
		Biochem. & Biophys. Res. Commun. 107(3):922-8 (1982)	
C	25	Reichel, H. and Norman, A., "Systemic Effects of Vitamin D," Ann. Rev. Med. 40:71-8 (1989)	
C	26	Scheddin, D. et al., "Synthesis and Biological Activities of 26-Hydroxy-27-Nor-Derivatives of 1-Alfa, 25-Dihydroxyvitamin D ₃ ," <i>Steroids</i> 61(10):598-608 (1996)	
C	27	Schwartz, G. et al., "1,25-Dihydroxy-16-ENE-23-YNE-Vitamin D ₃ and Prostate Cancer Cell	
		Proliferation in Vivo," <i>Urology</i> 46(3):365-9 (1995)	
C	28	Siu-Caldera, ML et al., "The Enhanced Biological Activities Ascribed to its Parent Analog, 1α , 25(OH) ₂ -16-ene-D ₃ ," <i>J. Steroid Biochem. Molec. Biol.</i> 59(5/6):405-12 (1996)	
C	29	Veyron, P. et al., "New 20-Epi-Vitamin D3 Analogs: Immunosuppressive Effects on Skin Allograft Survival," <i>Transplantation Proceedings</i> 27(1):450 (1995)	

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Examiner	/Taofiq Solola/	Date	11/17/2008
Signature		Considered	

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

Attorney Docket No.: 60188CON2(49947)

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Perer C. Lauro

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Signature:

(Peter C. Lauro, Esq.)

Docket No.: 60188CON2(49947)

(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Ratent Application of: Reddy, Satyanarayana G.

Application No.: 10/750570

Confirmation No.: 5729

Filed: December 30, 2003

Art Unit: 1614

For: Cyclic Ether Vitamin D3 Compounds,

Examiner: Not Yet Assigned

1α(OH)3-EPI- Vitamin D3 Compounds and

Uses Thereof

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Respectfully submitted,

Peter C. Laure, Esq.

Registration No.: 32,360 EDWARDS & ANGELL, LLP

P.O. Box 55874

Boston, Massachusett 02205

(617) 439-4444

Attorney for Applicant

Customer No.: 21874